

Exhibit G

SHARI ALLEN O'QUINN - Direct

1 product release, and those actions could have been an
2 additional review or further investigations.

03:26:22

3 Q. So in response to that finding that this had reached a
4 quad level three with reports of caudal migration, did the
5 company, in fact, institute further action?

03:26:37

6 A. Yes.

7 Q. And what was that further action?

8 A. We continued to conduct an evaluation of these events and
9 we had a physician come out and review the events with us and I
10 personally reviewed them with him to determine if there was a
11 concern about these events.

03:26:56

12 Q. Did you meet with a number of experts in the field
13 concerning these reports of caudal migration?

14 A. Yes.

15 Q. Did you convene a meeting in Chicago with experts?

03:27:16

16 A. Yes.

17 Q. Did you attend that meeting?

18 A. Yes.

19 Q. And did you consult with various experts throughout the
20 country in the interventional radiology field about the
21 significance of caudal migration?

03:27:25

22 A. Yes.

23 Q. And did you notify the FDA about what the company had
24 found under its DFMEA with regard to caudal migrations?

25 A. Yes.

03:27:42

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1 Q. Let me show you what's been marked as 5881. Have you seen 03:27:42
2 5881 before?

3 A. Yes.

4 Q. And who is Cynthia Walcott who signed this letter?

5 A. She was the person in our Quality Department that was 03:28:30
6 responsible for the evaluation of these events called MDRs,
7 medical device reports.

8 Q. When the Quality Department was corresponding directly to
9 the FDA in response to various inquiries, were those responses
10 generally reviewed by you and your department? 03:28:51

11 A. Not all of them but many of the correspondences were
12 reviewed by my department, if it was anything other than just a
13 routine clarification or simple information.

14 Q. Would a letter of this nature be reviewed do you believe?

15 A. Yes. 03:29:10

16 Q. And why is that?

17 A. It was because it was requesting specific information
18 about the event that was more detailed other than just a
19 clarification or more clerical type clarification to the
20 report. 03:29:27

21 Q. Was this maintained in the company's files as a business
22 record.

23 A. Yes. We maintained those in the MDR report files.

24 MR. NORTH: Your Honor, at this time I would tender
25 5881. 03:29:39

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MR. O'CONNOR: No objection.

THE COURT: Admitted.

(Exhibit Number 5881 was admitted into evidence.)

MR. NORTH: Could we display, Your Honor?

THE COURT: Yes.

BY MR. NORTH:

Q. Let's look on the second page at number four. In this letter, did the company notify the FDA that in its analysis of caudal migration in the DFMEA as it was originally constituted, the caudal migration rate was found to be an issue?

A. Yes.

Q. And what did the company tell the FDA that it had done in response to this finding?

A. That we had reassessed as part of our evaluation and we had deemed that it remains below the clinical risk threshold and that it remains acceptable.

Q. Well, why did you change the threshold? What justified changing the threshold for caudal migrations?

MR. O'CONNOR: Objection.

THE WITNESS: Lack of foundation, Your Honor.

THE COURT: Sustained. I think you need to lay foundation.

BY MR. NORTH:

Q. Were you involved on the investigative team as a part of the process of changing the threshold definition for caudal

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migrations?

03:31:14

A. Yes.

Q. And was that something the team did together?

A. Yes.

Q. Can you tell us now what the basis of the team's decision was regarding the threshold for caudal migrations under the DFMEA?

03:31:22

A. Yes. The --

MR. O'CONNOR: Still objection, lack of foundation in terms of what method was used.

03:31:36

THE COURT: Overruled.

BY MR. NORTH:

Q. You may answer.

A. Okay. It was based upon feedback from the physicians that said that if the event was asymptomatic, it shouldn't be part of the same threshold rate that was originally established for Recovery because that was based upon all migrations, including the cephalad, towards the heart, and that there had been no indication that the caudal migrations had resulted in any clinical events.

03:31:48

03:32:15

Q. Did the FDA protest or question the decision to reassess that threshold given the difference between caudal and cephalad migrations?

MR. JOHNSON: Objection. Hearsay.

THE COURT: Depends on what the answer is.

03:32:36

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1 BY MR. NORTH:

03:32:38

2 Q. Just -- let me rephrase if I could.

3 THE COURT: All right.

4 BY MR. NORTH:

5 Q. Did the FDA ever indicate to you any concern about the
6 change in the threshold because of the difference between
7 caudal and cephalad migrations?

03:32:42

8 MR. O'CONNOR: Objection, hearsay.

9 THE COURT: It's the same question. It depends on
10 the answer. If she says no, it's not hearsay. If says yes,
11 it's hearsay.

03:32:57

12 MR. NORTH: Well, I wouldn't ask her the follow-up
13 question which is what did they say.

14 THE COURT: Overruled.

15 THE WITNESS: I can answer it?

03:33:13

16 BY MR. NORTH:

17 Q. Yes, you may answer. I'm sorry.

18 A. No, they did not.

19 Q. If we could look at Exhibit 5879, please. Is this another
20 letter sent to the FDA? If we could look at the second page
21 here, too. Is this a follow-up letter sent by Ms. Walcott to
22 the FDA about the same topic?

03:33:40

23 A. Yes. It was about the DFMEA.

24 Q. And was this, again, sent to the FDA after a review by you
25 and/or your department?

03:34:02

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1 A. Yes.

03:34:03

2 Q. And was this maintained in the regular business records of
3 the company?

4 A. Yes.

5 MR. NORTH: Your Honor, at this time we would tender
6 5879.

03:34:09

7 MR. O'CONNOR: I'm looking at it Your Honor. It's
8 hearsay within hearsay.

9 THE COURT: Where are you looking?

10 MR. O'CONNOR: Page two, for example, the table and
11 the lack of foundation for whoever made that table.

03:34:26

12 THE COURT: Overruled. I think it's a business
13 record. 5879 is admitted.

14 (Exhibit Number 5879 was admitted into evidence.)

15 MR. NORTH: May we publish, Your Honor?

03:34:53

16 THE COURT: Yes.

17 BY MR. NORTH:

18 Q. If we could look at the first page at the bottom of the
19 page, the last two paragraphs. Did Bard here provide the FDA
20 with further explanation regarding the DFMEA and the adjustment
21 to the threshold?

03:35:15

22 A. Yes.

23 Q. And then if we could look at 5880 and could we look at the
24 second page. Is this another follow-up from Ms. Walcott?

25 A. Yes.

03:36:16

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1 Q. And was this, again, prepared with input from you or your
2 department?

03:36:18

3 A. Yes.

4 Q. And was this maintained as a business record?

5 A. Yes.

03:36:25

6 Q. And was this, again, addressing caudal migrations?

7 A. Yes.

8 MR. NORTH: Your Honor, at this time we would tender
9 5880.

10 MR. O'CONNOR: No objection.

03:36:38

11 THE COURT: Admitted.

12 (Exhibit Number 5880 was admitted into evidence.)

13 MR. NORTH: Is 5539 admitted?

14 COURTROOM DEPUTY: No.

15 MR. NORTH: Could we display 5539?

03:36:59

16 BY MR. NORTH:

17 Q. Was a formal Failure Investigation Report prepared
18 regarding the investigation into caudal migration?

19 A. Yes.

20 Q. And were you a signatory to that report?

03:37:17

21 A. Yes.

22 Q. Is this a copy of that report?

23 A. Yes.

24 Q. Was it maintained in the company's business files?

25 A. Yes.

03:37:26

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1 Q. And was it prepared with direct input from you?

03:37:27

2 A. Yes.

3 MR. NORTH: Your Honor, at this time I would tender
4 5539.

5 MR. O'CONNOR: May I see the second page?

03:37:36

6 THE COURT: Please.

7 MR. O'CONNOR: No objection.

8 THE COURT: Admitted.

9 (Exhibit Number 5539 was admitted into evidence.)

10 BY MR. NORTH:

03:38:00

11 Q. During the entire time there, did the company -- your
12 entire time there, did Bard continue to track adverse event
13 reports with the G2 filter?

14 A. Yes.

15 Q. Including all reports of caudal migration?

03:38:13

16 A. Yes.

17 Q. Did the company ever, as far as your involvement or
18 knowledge, reach a determination that the risks of the device
19 were outweighing the benefits?

20 A. No.

03:38:25

21 Q. And after the adjustment was made to the threshold based
22 upon the difference between the severity of cephalad migrations
23 versus caudal migrations, was there ever a time when the rate
24 of caudal migrations triggered a finding of unacceptable?

25 A. No.

03:38:45

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MR. O'CONNOR: Objection. Lack of foundation.

THE COURT: Overruled.

BY MR. NORTH:

Q. Ms. Allen, you were there with Bard Peripheral Vascular when these reports came in regarding people dying, perhaps associated with the migration of the Recovery filter; correct?

A. Yes.

Q. And was that difficult for you?

A. It was. It was very difficult and we took those very seriously. We were constantly evaluating these rates because we cared tremendously about the patients that our products served.

Q. Even though you were receiving these reports of a small number of incidents of migrations and death with the Recovery filter, did you and your colleagues, to your knowledge, reach a conclusion that the risks of the Recovery filter outweighed its benefits?

A. No.

Q. Did you continue to believe that the Recovery filter provided a valuable therapeutic tool to doctors?

A. Yes, I did, and one of my family members received the product.

MR. O'CONNOR: Object. Irrelevant, Your Honor.

THE COURT: Overruled.

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SHARI ALLEN O'QUINN - Cross

1 BY MR. NORTH:

03:40:24

2 Q. I'm sorry. Could you repeat what you just said?

3 THE COURT: She said the answer.

4 MR. NORTH: Okay.

5 BY MR. NORTH:

03:40:33

6 Q. During your entire time with the G2 filter working with
7 that, did you ever find a problem or see a problem that made
8 you believe that the risks of the product outweighed its
9 benefits?

10 A. No.

03:40:43

11 Q. And during your entire time when you were working with the
12 G2 filter, did you believe it provided a valuable therapeutic
13 benefit to patients?

14 A. Yes, I did.

15 Q. Thank you.

03:40:54

16 MR. NORTH: That's all the questions I have.

17 THE COURT: Cross-examination?

18 **CROSS - EXAMINATION**

19 BY MR. O'CONNOR:

20 Q. Good afternoon. It's Mrs. O'Quinn?

03:41:28

21 A. Yes. My name, when I was at Bard, was Allen and I have
22 gotten married and -- or actually divorced and changed my name
23 back to my maiden name of O'Quinn.

24 Q. Okay. You're O'Quinn, I'm O'Connor. Mark O'Connor. I've
25 never met you before but nice to meet you today.

03:41:46